



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

FEB 27 1998

2579 '98 MAR 17 P1:40

Ms. Gale Bensussen
President
Leiner Health Products
901 E. 233rd Street
Carson, California 90745-6204

Dear Ms. Bensussen:

This is in response to your letter of February 2, 1998 to the Food and Drug Administration (FDA) pursuant to 21 USC 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Leiner Health Products is making the following statements, among others, for the following products:

YourLife Saw Palmetto

"...can play an important part in maintaining normal urinary flow in many men over 50"

Spring Valley Ginkgo Biloba

"...means to help maintain cerebral circulation which may become reduced or weakened with age"

21 USC 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The claims that you are making for these products suggest that they are intended to treat, prevent, or mitigate disease, in that they are intended to treat, prevent, or mitigate benign prostatic hypertrophy and cerebral vascular disease. These claims do not meet the requirements of 21 USC 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 USC 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 104

Page 2 - Ms. Gale Bensussen

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, JGordon)

HFS-456 (file)

HFS-450 (r/f, file, OSN#57056)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:2/10/98

init:GCF-1:DDorsey:2/13/98

f/t:rjm:HFS-456:2/17/98:57056.adv:disc25

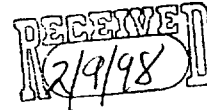


57056

901 E. 24th Street
Carson, California
90745-0204
Tel: 310-582-1100
Fax: 310-582-1101

February 2, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW
Washington, DC 20204



Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

Prostate Well Being

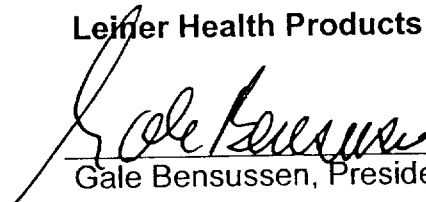
European men have been supplementing their diet for many years with saw palmetto. Regular use of saw palmetto extract can play an important part in maintaining normal urinary flow in many men over 50.

on the following product:

YourLife® Saw Palmetto

Very truly yours,

Leiner Health Products


Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs
William Cochran, Regulatory Affairs Associate



900 E. 21st Street
Culson, California
90747-6201
Tel: 818-330-1100
Fax: 818-330-1101

January 28, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW
Washington, DC 20204

2/4/98

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following and statements:

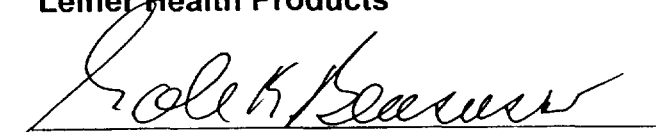
Ginkgo Biloba has been used for centuries to help promote healthy circulation. It has gained popularity in recent years as a natural means to help maintain cerebral circulation which may become reduced or weakened with age.

on the following product:

Spring Valley ® Ginkgo Biloba

Very truly yours,

Leiner Health Products


Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs
William Cochran, Regulatory Affairs Associate

57056